

LAMPIT is the only FDA-approved treatment for Chagas disease caused by the parasite *Trypanosoma cruzi* for children of all ages, from birth to younger than 18 years, who weigh at least 5.5 pounds (2.5 kg)

What is LAMPIT?

LAMPIT® is a prescription medicine used to treat Chagas disease caused by the parasite *Trypanosoma cruzi* in children less than 18 years of age weighing at least 5.5 pounds (2.5 kg). It is not known if LAMPIT is safe and effective in children weighing less than 5.5 pounds (2.5 kg).

Important Safety Information

Do not take LAMPIT tablets if you:

- Are allergic to nifurtimox, or any of the ingredients in LAMPIT
- Plan to drink alcohol during treatment with LAMPIT

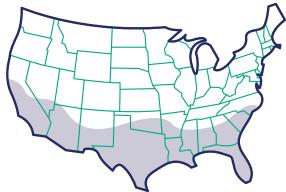
Please see Important Safety Information throughout this brochure and the <u>full Prescribing Information</u>.



Chagas disease is caused by an infection and can become serious if it is not treated

Chagas disease is caused by a parasite called *Trypanosoma cruzi*, which is transmitted to humans by insects referred to as "kissing bugs."

As many as **300,000** people in the United States may be infected with Chagas disease.





How is it spread?

Although Chagas disease is most often spread to people by kissing bugs, it can also spread:

- From pregnant mothers to their unborn children
- Through organ transplantation or blood transfusions
- By eating contaminated food

Who is at risk of Chagas disease?

People are at risk if they live in an area where Chagas disease is common. Babies whose mothers had the infection during pregnancy are at risk of Chagas disease and should be tested after birth.

What are some symptoms of Chagas disease?

Soon after being infected, people may have mild to moderate symptoms, such as:









Fever

Body aches

Tiredness

Swelling around the site of the bug bite

Children sometimes develop a swollen eyelid on the side of the face that was bitten. Even though these symptoms may go away after a few weeks, the infection may remain for years, sometimes causing serious problems.



How is Chagas disease diagnosed and treated?

Chagas disease may be **diagnosed with blood tests** and may be treated with medicine.



It is important to diagnose and treat Chagas disease early. People may develop a lifelong infection that causes severe damage to their heart and gut. If you think your child may be at risk, talk with your doctor about testing and medicine to treat the infection.

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LAMPIT® (nifurtimox) is a medicine approved for treatment of Chagas disease:

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- If your child has been diagnosed with Chagas disease, ask your doctor about LAMPIT
- Treating Chagas disease early is recommended

How to take LAMPIT

LAMPIT is a tablet that is taken 3 times a day with food. Your doctor will determine the dose based on how much a child weighs.



It is important to take LAMPIT exactly as directed.

See the detailed Instructions for Use in the Prescribing Information for important use instructions.

You can find more information on how to take LAMPIT here.

Important Safety Information (continued)

Before taking LAMPIT, tell your healthcare provider about all your medical conditions, including if you:

- have a history of brain injury, seizures, mental health problems or behavioral changes.
- have kidney problems or are on dialysis.
- have liver problems.
- have a genetic problem called porphyria. Taking LAMPIT can make your symptoms of porphyria including dark urine, severe stomach pain, muscle pain, tingling, numbness, mental changes or skin sensitivity to light worse.
- are pregnant, plan to become pregnant, or think you may be pregnant. LAMPIT can harm your unborn baby.

Please see Important Safety Information throughout this brochure and the <u>full Prescribing Information</u>.

What are the most common side effects of LAMPIT?

The most common side effects of LAMPIT include:

- - Decreased appetite
- Fever

- Abdominal pain
- Nausea

Rash

• Headache

Vomiting

These are not all of the possible side effects of LAMPIT. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.



Important Safety Information (continued)

For females who are able to become pregnant:

- Your healthcare provider should do a pregnancy test before you start taking LAMPIT to make sure that you are not pregnant.
- You should use effective forms of birth control during treatment with LAMPIT and for 6 months after your last dose of LAMPIT. Talk to your healthcare provider about what forms of birth control may be right for you.
- Call your healthcare provider right away if you become pregnant or think you are pregnant during treatment with LAMPIT.

For males:

- LAMPIT may cause fertility problems in males. This may affect your ability to father a child. Talk to your healthcare provider if you have concerns about fertility.
- You should use a condom with female partners who are able to become pregnant, during treatment with LAMPIT and for 3 months after your last dose of LAMPIT.
- are breastfeeding or plan to breastfeed. LAMPIT can pass into breast milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby during treatment with LAMPIT. If you take LAMPIT and breastfeed, monitor your baby for vomiting, rash, decreased appetite, fever, and irritability.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.



Programs that may help with the cost of LAMPIT® (nifurtimox) treatment

Bayer is committed to helping people with Chagas disease who are prescribed LAMPIT get the treatment they need.

Bayer understands that sometimes people face financial challenges, and for those who are eligible, we have developed a program to help.

Here is a program that may help.

The Bayer US Patient Assistance Foundation



- For eligible uninsured patients who cannot afford LAMPIT, the Bayer US Patient Assistance Foundation is a charitable organization that may help eligible patients get their LAMPIT prescription at no cost
- For more information, visit the foundation website at **PatientAssistance.Bayer.us**

Important Safety Information (continued)

What are the possible side effects of LAMPIT? LAMPIT may cause serious side effects, including:

- Worsening of symptoms related to brain injury, seizures, mental health problems or behavior changes in people with a history of these problems. Call your healthcare provider right away if any of these problems get worse during treatment with LAMPIT.
- Allergic reactions. Allergic reactions can happen when taking nifurtimox, the active ingredient in LAMPIT, or with changes in your immune system caused by Chagas disease during treatment with LAMPIT. These allergic reactions can include low blood pressure, swelling of the face and tongue (angioedema), shortness of breath, itching, rash or other skin problems. Call your healthcare provider or get emergency medical help if you get any of these signs and symptoms of an allergic reaction during treatment with LAMPIT.

Please see Important Safety Information throughout this brochure and the <u>full Prescribing Information</u>.

Important Safety Information (continued)

What are the possible side effects of LAMPIT? (continued) LAMPIT may cause serious side effects, including:

• Loss of appetite and weight loss. Your healthcare provider should check your weight every 14 days to see if your dose of LAMPIT may need to be changed.

The most common side effects of LAMPIT include: vomiting, abdominal pain, headache, decreased appetite, nausea, fever, and rash.

These are not all the possible side effects of LAMPIT. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

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If your child has Chagas disease, LAMPIT® (nifurtimox) may help

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Bayer offers a program that may help with costs and access to LAMPIT for eligible patients

 To find out more program details, visit <u>PatientAssistance.Bayer.us</u>

Talk with your doctor if you think your child may have or is at risk of Chagas disease, and to find out if LAMPIT is right for them.

For more information about Chagas disease and LAMPIT, visit <u>LAMPIT.com</u>.

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